February 15, 2023

Robert M. Califf, MD, MACC
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
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Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
2877 Brandywine Rd, Room 2402
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Drs. Califf and Walensky,

The COVID-19 pandemic brought many challenges that the health and medical field have never encountered. Although the initial response was led by a sense of urgency and crisis management, I believe it is critical that as public health professionals, responses are adapted to the present to chart a future guided by data and common sense.

As Florida's Surgeon General, it was in the public's best interest to issue guidance for using mRNA COVID-19 vaccines in children and in young men based on the absence of a health benefit in clinical trials. This guidance followed preliminary data analyses by the Florida Department of Health. We continue to refine and expand these findings, including addressing methodological issues inherent to evaluating vaccine safety and efficacy.

In addition to Florida's analysis of mRNA COVID-19 vaccines, academic researchers throughout our country and around the globe have seen troubling safety signals of adverse events surrounding this vaccine. Their concerns are corroborated by the substantial increase in VAERS reports from Florida, including life-threatening conditions. We have never seen this type of response following previous mass vaccination efforts pushed by the federal government. Even the H1N1 vaccine did not trigger this sort of response. In Florida alone, we saw a 1,700% increase in reports after the release of the COVID-19 vaccine, compared to an increase of 400% in vaccine administration for the same period. The reporting of life-threatening conditions increased 4,400%.

This increase in adverse events, compared to the percent increase in vaccine use, further explains the significant uptick we are seeing in VAERS reports. These findings are unlikely to be related to changes in reporting given their magnitude, and more likely reflect a pattern of increased risk from mRNA COVID-19 vaccines. We need unbiased research, as many in the

academic community have performed, to better understand these vaccines' short- and long-term effects.

According to a recent study, mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events, including coagulation disorders, acute cardiac injuries, Bell's palsy, and encephalitis, to name a few. This risk was 1 in 550, much higher than other vaccines. To claim these vaccines are "safe and effective" while minimizing and disregarding the adverse events is unconscionable.

Communication between physicians and patients is a standard ethical practice that is fundamental to public health. Health care professionals should have the ability to accurately communicate the risks and benefits of a medical intervention to their patients without fear of retaliation by the federal government.

The State of Florida remains dedicated to responding to COVID-19 and other public health concerns through data-driven decisions. We will continue to shed light on the safety and efficacy of medications, including mRNA COVID-19 vaccines, that could be an imminent threat to those with preexisting conditions. We will also promote the importance of prevention by supporting good nutrition, exercise, and other healthy habits. As a father, physician, and Surgeon General for the State of Florida, I request that your agencies promote transparency in health care professionals to accurately communicate the risks these vaccines pose. I request that you work to protect the rights and liberties that we are endowed with, not restrict, and diminish them.

I look forward to your responses and appreciate your support of our collective efforts to serve the health and safety of Florida and our nation.

Sincerely,

Joseph A. Ladapo, MD, PhD
State Surgeon General